UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION

Master File No. 12-995 (WHW-MCA)

THIS DOCUMENT RELATES TO:

ALL ACTIONS

Motion Day: November 5, 2012

TEVA'S OPPOSITION TO FTC'S MOTION TO FILE AMICUS BRIEF

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Defendants Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva") hereby oppose the motion filed by the Federal Trade Commission ("FTC") for Leave to File Amicus Curiae Brief. (Dkt. No. 89.) Teva submits that the FTC is hardly an "independent" observer as its motion would pretend. The FTC is an active litigant in other so-called "reverse payment" cases and has unsuccessfully lobbied Congress for years to adopt legislation consistent with the FTC's views, and its efforts have been rebuffed by both Congress and the courts.1 But even apart from its clear bias, the FTC's motion is ill-founded. The FTC's proposed amicus memorandum ("FTC Br."), is the Commission's most recent attempt to inject its failed litigation and legislative lobbying position into a private lawsuit to which it is not a party. Such an effort was rejected by this Court less than a month ago.² The FTC's biased and repetitive amicus memorandum adds nothing to the briefing on Defendants' Motions to Dismiss (Dkt. Nos. 71, 72), and the Court should deny the FTC's request for leave.³

¹ See, e.g., FTC v. Cephalon, Inc., No. 08-cv-2141-MSG (E.D. Pa.); FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012); Preserve Access to Affordable Generics Act S. 27, 112th Cong. (2011); S. 369, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009).

² See Oct. 3, 2012 Order denying FTC's Motion for Leave to File Amicus Curiae Brief, Professional Drug Co., Inc. v. Wyeth Inc., Civ. Action No. 11-5479 (JAP) (Dkt. No. 187) ("Pisano Order").)

For example, the FTC repeatedly cites documents regarding parties and agreements not before the Court. See, e.g., FTC Br. at 5-10. But none of those

However, if the Court were to accept the FTC Brief, it should reject the FTC's overbroad interpretation of *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). Among other things, the FTC Brief construes *K-Dur* far more broadly than the Third Circuit gave any reason to believe it intended, and its interpretation would render presumptively illegal a common type of exclusive patent litigation settlement.

I. The Court Should Deny the FTC's Request for Leave to File an *Amicus*Brief

As an initial matter, the FTC is not a party to this litigation and thus has no inherent right to file a brief in this matter. Nor is the FTC entitled to intervene at this level simply by virtue of the fact that it is a government agency. The provision the FTC seeks to interpret, 15 U.S.C. § 1 is not a delegation of regulatory authority to an agency but a legal right enforceable in court. "Congress established an enforcement scheme independent of the Executive and provided aggrieved [parties] with direct recourse to federal court where their rights under the statute are violated. Under such circumstances, it would be inappropriate to consult executive interpretations of [the provision] to resolve ambiguities surrounding the scope of [the statute's] judicially enforceable remedy." *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990); *see also Crandon v. United States*, 494 U.S.

agreements or documents is alleged to have any connection or similarity to the agreement at issue in this case, and all are therefore irrelevant.

152, 177 (1990) (Scalia, J., concurring in judgment) (rejecting *Chevron* deference where the statute "is not administered by any agency but by the courts").

The FTC's amicus brief seeks only to promote an interpretation of the Sherman Act, a role clearly within the core competency of this Court. Unlike where a government agency offers an interpretation of its own regulations, such that courts must grant *Chevron* deference, *Auer v. Robbins*, 519 U.S. 452, 461 (1997), *Chase Bank USA, N.A. v. McCoy*, 131 S. Ct. 871, 880 (2011), here the agency merely advocates for an approach to patent settlements that neither the courts nor the legislature has adopted, and no deference is due. *See Keys v. Barnhart*, 347 F.3d 990, 993-94 (7th Cir. 2003); *M. Fortunoff of Westbury Corp. v. Peerless Ins. Co.*, 432 F.3d 127, 139 (2d Cir. 2005). Because it acts here as an advocate for a litigation and legislative position rather than a neutral agency, the FTC is due no deference in this proceeding. *See Chavez-Rivas v. Olsen*, 207 F. Supp. 2d 326, 332 (D.N.J. 2002).

While courts have discretion in the treatment of *amicus* filings, they generally deny leave when the *amicus* submission seeks simply to advocate a litigation position rather than provide guidance on the issues before the court.⁴ See

⁴ As one court warned, "[t]he vast majority of amicus curiae briefs are filed by allies of litigants and duplicate the arguments made in the litigants' briefs, in effect merely extending the length of the litigant's brief. Such amicus briefs should not be allowed. They are an abuse. The term 'amicus curiae' means friend of the court, not friend of a party." Ryan v. Commodity Futures Trading Comm'n, 125

Ryan v. Commodity Futures Trading Comm'n, 125 F.3d 1062, 1063-64 (7th Cir. 1997); Strasser v. Doorley, 432 F.2d 567, 569 (1st Cir. 1970); Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp., 149 F.R.D. 65, 82-83 (D.N.J. 1993). "Amicus status is typically granted when: (1) the amicus has a 'special interest' in the particular case; (2) the amicus' interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the amicus is not partial to a particular outcome in the case." United States v. Alkaabi, 223 F. Supp. 2d 583, 592 (D.N.J. 2002). "At the trial level, where issues of fact as well as law predominate, the aid of amicus curiae may be less appropriate than at the appellate level where such participation has become standard procedure." Id. at 592 n.16 (quoting Yip v. Pagano, 606 F. Supp. 1566, 1568 (D.N.J. 1985)). The FTC Brief serves no other purpose than advocating a litigation position, and the Court should deny leave for the following reasons.

A. The FTC Does Not Express A Special Interest And Seeks To Repeat Arguments Already Made By Plaintiffs

The FTC's motion should be denied because it does not express a special interest "not represented competently" in this case. *Alkaabi*, 223 F. Supp. 2d at 592 (relied upon by FTC). The FTC, a non-party, simply wishes to argue that GlaxoSmithKline's ("GSK") exclusive license to Teva (which by definition precluded GSK from launching an authorized generic ("AG") during the license

period) should be viewed as anticompetitive. The FTC seeks leave to advocate a rule that literally any "value," not limited to cash, flowing from the patent-holder to the alleged infringer constitutes a "reverse payment" and should be subject to a presumption of anticompetitive effect under *K-Dur*. But that is the same argument – one that defendants have shown is baseless – that plaintiffs in this case have already made. (*See, e.g.*, Am. Compl., Dkt. No. 55, ¶¶ 20, 23, 26, 69, 74, 80-83, 90; Direct Purchaser Pls.' Opp'n to the Mots. to Dismiss Filed by Defs. GSK and Teva ("Direct Purchaser Br."), Dkt. No. 86, at 26-31.)

While the Commission has advocated for such a broad construction as a litigant for over ten years, it has been rebuffed by court after court. See, e.g., F.T.C. v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012), pet for cert. filed (U.S. Oct. 4, 2012) (No. 12-416). Indeed, even in K-Dur the FTC advanced this same argument, and, as discussed below, the argument was not adopted by the court. In addition, the Commission has advocated this same view before Congress, but the resulting legislation has repeatedly failed to pass. See [Preserve Access to Affordable Generics Act, S. 369], 111th Cong. (2009); [S. 316 110th Cong. (2007)]; [H.R. 1432, 110th Cong. (2007)]; [S. 3582, 109th Cong. (2006)]; [Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009)]; [H.R. 1902, 110th Cong. (2007).] Moreover, the Commission's proposed submission merely repeats passages from publicly available reports and studies –

the very reports and studies that Plaintiffs have made substantial use of themselves.⁵ These studies were performed against the backdrop of the FTC's *litigation* goal of achieving the invalidation of pharmaceutical patent settlements involving any value running from the patent holder to the generic infringer, *see*, *e.g.*, *Watson*, 677 F.3d 1298, *Schering-Plough Corp.* v. F.T.C., 402 F.3d 1056 (11th Cir. 2005), and have been criticized as being slanted in various ways in light of that litigation goal.⁶

As recently noted by Judge Pisano:

[T]he study relied upon by the FTC in its proposed brief is publicly available and has been cited by the Plaintiffs in their briefing to this Court. Plaintiffs are represented by competent counsel who have ably addressed the relevant issues relating to the motions to dismiss. Doing little more than duplicating arguments raised by the parties is not the proper role of an amicus curiae.

⁵ See, e.g., Federal Trade Comm'n, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (2011) ("FTC Study"); Direct Purchaser Br., Dkt. No. 86, at 13-14 (quoting FTC Study).

⁶ See, e.g., C. Kyle Musgrove and Richard Ripley, Reverse Payment Settlements: Presumptively Bad or Usually Acceptable, CPI Antitrust Chronicle, June 2012; Richard S. Higgins, Rule-Of-Reason Analysis Of Pay-For-Delay Settlements, Law360, August 8, 2012, available at http://www.law360.com/articles/365460/rule-of-reason-analysis-of-pay-for-delay-settlements ("It is highly likely that [the FTC Study's] sample of infringement suits litigated to judgment is not representative of all patent infringement suits and that statistics regarding patent validity derived from it are biased.").

(Pisano Order at 3 (citing *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)).) Having another interested party "pile on" with an additional brief is not warranted.

B. The Proposed FTC Brief Will Not Be Useful To The Court In Resolving The Pending Motions To Dismiss

It is simply improper for an interested plaintiff such as the FTC to "interpret" the Third Circuit's jurisprudence for this Court. And it is hardly necessary or useful. The K-Dur court explicitly limited its holding to monetary payments. The court "caution[ed] that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry." K-Dur, 686 F.3d 197 at 216. The term "reverse payment" has an established definition: "Reverse payment' patent settlements" are those "in which the patentee explicitly pays the alleged infringer to stay out of the market." Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J. sitting by designation). The Third Circuit provided a definition of "reverse payment agreements" as "settlement agreements in which the patent holder paid the would-be generic manufacturer to drop its patent challenge and refrain from producing a generic drug for a specified period." K-Dur, 686 F.3d at 204 (emphasis added). Clearly the court was referring to monetary payments, given the court's chosen language: "the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand

manufacturer to the generic challenger." *Id.* at 218. The *K-Dur* court could have noted the FTC's concerns and expanded its test beyond settlements involving a "cash payment," *id.* at 205, or "money that changed hands," *id.* at 218. But it did not.

Additionally, the FTC's brief is not likely to be helpful because none of its prior statements regarding "AG Delay" provisions dealt with a license for which a royalty was paid by the *infringer* to the *patent holder*. The FTC's comments have nothing to do with the kind of provision at issue in this case.

C. The FTC Is Partial To The Outcome Of This Litigation

By its own admission, the FTC seeks to inject the record in this case with biased, flawed, and inadmissible material under the guise of "data" from a study authored by none other than the FTC itself. (See FTC Mem. In Support at 5.) The FTC flatly states that its amicus brief "presents data" from a study "conducted by the FTC" regarding authorized generics. (Id.) In the King Drug case, the district judge criticized plaintiffs for attempting to inject similar FTC "studies" into the record on a motion to dismiss. See FTC v. Cephalon, Inc., No. 08-cv-02141-MSG (E.D. Pa.) July 28, 2009 Tr. at 49 (Dkt. No. 39) (indicating that the court decides "as a matter of law, whether the actions that have been filed go forward or not, and whether the FTC did a study or not" did not seem to be "something appropriate to look at"). Moreover, such "evidence" is unsupported, and the FTC's "amicus"

brief is simply an advocacy piece for its own flawed studies. The FTC's "AG Study," like its prior "Pay for Delay Study" is biased advocacy of the FTC's litigation and legislative positions, and its conclusions are flawed and untested. See, e.g., B. Dickey, J. Orszag & R. Willig, A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements 3 at (Aug. 10, 2010), available at http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Wi llig%20CBO.pdf (concluding that "the FTC analysis is unreliable" because the study "oversimplified the analysis in a way that has material bearing on its utility and reliability"); C. Davis et al., FTC Call for Settlement Ban Is . . . Full of Sound and Fury, Signifying Nothing 1-5 (Jan. 14, 2010) (concluding that the FTC study was "exceedingly flawed" because, inter alia, it "presume[d] patent invalidity across the board"). In short, the FTC seeks to present "evidence" that is wellbeyond the pleadings and thus improper to be considered in the context of a Rule 12(b)(6) motion. See, e.g., Price v. Corzine, Civ. No. 06-1520 (GEB), 2006 WL 2252208, at *3 (D.N.J. Aug. 7, 2006) (denying ACLU's motion to participate amicus curiae and noting that "its participation would not be useful to the Court in evaluating Defendants' motion [to dismiss].").

Additionally, the FTC cannot reasonably argue that it is simply "interested in the development of the law concerning reverse-payment settlements." (FTC Br.

at 4.) Teva submits that the FTC is *extremely* "partial to a particular outcome in this case." Judge Pisano, who recently found that the FTC is indeed partial to the outcome of similar proceedings, explained:

[H]istorically, the term amicus curiae has been used to describe an impartial individual who suggests the interpretation and status of the law, gives information concerning it, and whose function is to advise in order that justice may be done, rather than advocate a point of view so that a cause may be won by one party or another. U.S. v. Farber, 2006 WL 2417272, at *1 (D.N.J. 2006) (internal quotation marks omitted). The Court recognizes that "there is no rule that the amicus must be impartial," however, the degree of partiality is an appropriate consideration for the court with regard to the appearance of an amicus curiae. Waste [Mgmt. of Pa., Inc. v. City of York], 162 F.R.D. [34,] 36 [(M.D. Pa. 1995)]. Here, it appears that the FTC, itself a litigant in past and present proceedings in which similar issues have arisen or may arise, is significantly partial to a particular outcome in this case.

(Pisano Order at 3-4 (emphasis added).) Rather than a "friend of the Court," the FTC has been a party to other proceedings within the Third Circuit and throughout the United States attacking alleged "reverse payment" settlements. See, e.g., King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514 (E.D. Pa. 2010); Watson, 677 F.3d 1298; Schering-Plough, 402 F.3d 1056. The purported amicus submission offers nothing new or different, as an amicus submission must, but instead seeks to further the FTC's goal of attacking alleged "reverse payment" settlements. As such, the FTC's request for leave should be denied.

II. The Court Should Reject The FTC's Request Particularly In Light Of The FTC's Decision Not To Take Action With Respect to the GSK-Teva Settlement

The FTC's delayed appearance in this matter is compounded by its decision not to object to the GSK-Teva settlement when it was first submitted to the Commission in 2005. The settlement was submitted to the Federal Trade Commission and U.S. Department of Justice in April 2005 pursuant to the Medicare Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, and both agencies chose not to voice any objection. The MMA requires pharmaceutical patent settlements to be filed with these agencies, so as to give the agencies the opportunity to object at the outset to agreements that either agency believes are in violation of the law – and also to give real world guidance to competitors trying to comply with the law. Neither agency took any action.

The FTC's inaction appeared to make clear that it made the affirmative decision not to act on the settlement agreements now sought to be challenged by Plaintiffs. Under these circumstances, the Court should reject the *amicus*

⁷ See, e.g., 149 Cong. Rec. S8692-93 (daily ed. June 26, 2003) (statement of Sen. Leahy) (MMA designed to "let the FTC and Justice look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of the law will be allowed to stand"); 149 Cong. Rec. S8430 (daily ed. June 24, 2003) (statement of Sen. Leahy) (MMA "ensur[es] that our law enforcement agencies have the information they need to take quick action")

submission from the FTC seven years after the Commission was given an opportunity to object to the GSK-Teva settlement.

III. Even If Accepted, The FTC's Amicus Brief Fails To Address The Issues Alleged In This Case And Therefore Adds Nothing

If the Court nonetheless is inclined to accept the FTC's proposed brief, Defendants submit that the Commission's *amicus* adds nothing, as it fails to address the facts alleged in this case, and instead advocates an overbroad interpretation of *K-Dur* – an interpretation that the FTC has advanced to the courts and to Congress and that has never been accepted. *See, e.g., Watson*, 677 F.3d 1298.

First, while the FTC asserts that literally anything of value constitutes a "payment" within the meaning of *K-Dur*, it ignores that the Third Circuit offered no definition of what would constitute a reverse payment beyond the outright cash payment before the court. Indeed, just as it does here, the FTC urged the Third Circuit in *K-Dur* to outlaw all settlements in which the patentee provides any "economic value to the challenger in any form." But the court did not adopt such a broad construction, instead limiting itself to "reverse payments" – terminology appropriate for the outright cash payments before it. *See K-Dur*, 686 F.3d at 218 (defendants may rebut presumption by showing that "any *money that changed hands* was for something other than a delay in market entry"); *id.* at 204 ("patent holder *paid* the would-be generic manufacturer") (emphases added). In an attempt

to expand the Third Circuit's language beyond its reasonable meaning, the FTC cites the definition of "payment" from Black's Law Dictionary. (See FTC Br. at 10 n.29.) The Third Circuit, however, never cited Black's, and if it had intended the term to be read so broadly it easily could have adopted the definition that the Commission had urged upon it. The fact that the court did not do so is telling.

Second, while the FTC devotes substantial attention to establishing the unremarkable proposition that an exclusive license is valuable to the licensee, as Judge Posner has pointed out, all settlements "involv[e] 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Asahi Glass*, 289 F. Supp. 2d at 994. The logical conclusion of the FTC's arguments is that it would be well-nigh impossible for any litigant to settle a patent case without the risk of violating the antitrust laws and having to defend itself from costly and protracted antitrust litigation.

Indeed, since any exclusive license could be viewed as conveying "value" to the licensee, the FTC's literalist definition of "payment" would call into question whole categories of licenses heretofore viewed as unremarkable. See, e.g., Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931, 949 (Fed. Cir. 1993) (exclusive license not anticompetitive); see also Gen. Talking Pictures Corp. v. W. Elec. Co.,

305 U.S. 124, 127 (1938); *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997). Nothing in *K-Dur* suggests the court meant its opinion to be read so broadly and in such an impractical manner. The *K-Dur* court gave no indication that it meant to adopt a rule that would turn such exclusive licenses into reverse payment deals. Such a reading of *K-Dur* would throw the patent system into disarray.⁸

Third, the FTC complains that Defendants, in noting that exclusive licenses were not before the court in *K-Dur*, must therefore be seeking to use "labels" rather than "economic reality" (as the Third Circuit described it) in determining what constitutes a reverse payment. (FTC Br. at 6 (citing *K-Dur*, 686 F.3d at 218).) But in using that language, the Third Circuit was not providing guidance on what constitutes a reverse payment. Instead, the court was explaining why it believed it appropriate, under a "quick look" rule of reason, to apply a presumption of anticompetitive effect to the cash payment at issue in that case. *See K-Dur*, 686 F.3d at 218.

When considered in context, this language strongly suggests that the Third Circuit would not apply a quick look presumption to the provisions at issue here.

As the Supreme Court has made clear again and again, presumptions of

This is because, as the court in *Cipro* recognized, any patent license can be viewed as a "settlement" of an incipient patent dispute. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 533 (E.D.N.Y. 2005).

anticompetitive effect are appropriate only after the courts have had significant experience with the practice at issue, and have determined that it is always or nearly always anticompetitive. See, e.g., Cal. Dental Ass'n v. F.T.C., 526 U.S. 756, 780-81 (1999); see also In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 318 n.14 (3d Cir. 2010). Settlements involving exclusive field-of-use licenses such as the one at issue here have not been the subject of judicial experience, let alone substantial experience. As noted, an exclusive license – or as the FTC pejoratively and erroneously terms it, a "pay-for-delay" provision – was not before the court in K-Dur. Nor has the FTC identified any other case considering such provisions in a pharmaceutical patent settlement. By contrast, the courts have substantial experience addressing settlements involving outright cash payments such as those before the court in K-Dur. In short, there is no basis to apply an anticompetitive presumption to the exclusive license at issue here.

The FTC asserts that an exclusive license is indistinguishable from a cash "payment." (FTC Br. at 9-10.) But this ignores that the exclusive license is the very means by which early generic entry (seven years prior to patent expiry) was effectuated, not a "payment" to delay competition. *See, e.g., Asahi Glass*, 289 F. Supp. 2d at 994 (alleged "reverse payment" settlement "led to increased competition" by allowing market entry). Moreover, the grant of an exclusive license in these circumstances provided nothing to Teva other than that which it

would eventually have been allowed under the six-month exclusivity period contemplated by the Hatch-Waxman framework – though seven years earlier.

Fourth, even if *K-Dur* were to apply here, the FTC takes no account of the fact, that the exclusive license at issue requires Teva to pay royalties to GSK. Where the alleged infringer pays the patent-holder for a license, the license simply cannot be viewed as a "reverse" payment within the meaning of *K-Dur*. The *K-Dur* court did not even consider such a license.

Finally, the FTC's overbroad interpretation of *K-Dur* is irrelevant in light of the fact that any appeal in this case, because of the centrality of the *Walker Process* and sham litigation allegations, should go to the Federal Circuit, which applies the scope of the patent standard. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807-08 (1988) (Federal Circuit has jurisdiction where plaintiffs' "right to relief necessarily depends on resolution of a substantial question of federal patent law"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335-36 (Fed. Cir. 2008) (appeal heard by Federal Circuit where plaintiffs asserted *Walker Process* claims and challenged patent settlement; court recognized patent settlement raised issues "protected by patent law"); *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000) (Federal Circuit has jurisdiction over claims arising from exclusive patent license).

In short, the FTC invites this Court to impractically construe *K-Dur* far more broadly than the Third Circuit gave any reason to believe it intended, and in the process render presumptively illegal a common type of exclusive patent settlement, all against the backdrop of no judicial experience suggesting that such licenses are always or nearly always anticompetitive. As a result, if the Court finds it necessary on the pending Motions, the Court should construe *K-Dur* reasonably and in light of the particular facts at issue in that case (specifically, the cash payments) that are not at issue here.

CONCLUSION

For the foregoing reasons, this Court should deny the FTC's motion for leave to file an *amicus* brief.

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